UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC., NORTON (WATERFORD) LTD., AND TEVA PHARMACEUTICALS USA, INC. Plaintiffs, v. AMNEAL PHARMACEUTICALS OF NEW YORK, LLC, AMNEAL IRELAND LIMITED, AMNEAL PHARMACEUTICALS LLC, AND AMNEAL PHARMACEUTICALS INC. Defendants.	Civil Action No. 2:23-cv-20964-JXN-MAH

PLEASE TAKE NOTICE that the Federal Trade Commission will move before Magistrate Judge Michael A. Hammer, on April 1, 2024, for an Order granting the Commission leave to file the attached amicus brief pursuant to the Court's minute entry at ECF No. 51. No party opposes this motion.

PLEASE TAKE FURTHER NOTICE that in support of the unopposed motion, the Federal Trade Commission will rely on the attached memorandum of law. A proposed order has also been submitted with this motion.

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MEMORANDUM IN SUPPORT OF THE FEDERAL TRADE COMMISSION'S UNOPPOSED MOTION FOR LEAVE TO FILE AS AMICUS CURIAE

The pending dispositive motions in this case raise significant competition issues with market-wide implications extending beyond the parties' private dispute. The Federal Trade Commission (FTC), as an independent agency charged with protecting competition, represents the public interest and brings important expertise to these proceedings.

By filing this patent infringement case under the Hatch Waxman Act, Teva has delayed FDA approval of Amneal's proposed inhaler product by up to 30 months. Amneal counterclaims that the patents at issue were not properly listed in the FDA's Orange Book. The FTC has long maintained that impeding entry of competitors through improperly listed patents can violate competition laws. Further, FTC staff recently addressed the specific patents at issue here, publicly calling for Teva to remove them from Orange Book.

The attached amicus brief addresses issues not fully explored in the party briefs, including (1) the extent to which device and device component patents may be properly listed in the Orange Book, including but not limited to the patents at issue in this case; (2) the harms that may result from improperly listing patents, particularly with regard to inhaler products; (3) the availability of standalone antitrust claims based on improper patent listings; and (4) the strong public interest against immunizing improper Orange Book listings from antitrust liability.

Thus, the FTC respectfully requests leave to file the attached amicus brief.

I. Courts Have Broad Discretion to Appoint Amicus Curiae and Look Favorably on Government Agencies Seeking Such Appointment

"District courts have broad discretion to appoint *amicus curiae*."[1] Although there is "no rule governing the appearance of an *amicus curiae* in the United States District Courts," courts in this District look to the Federal Rules of Appellate Procedure for guidance in exercising their broad discretion.[2] Rule 29 of the Federal Rules of Appellate Procedure distinguishes between amicus briefs filed by federal governmental agencies and those filed by private parties. Unlike amicus briefs filed by private parties, those from federal agencies are accepted by Courts of Appeals as a matter of right,[3] and some courts in this district have accepted amicus filings solely on that basis.[4] Favorable treatment of proposed amicus filings by the federal government reflects the understanding that "governmental bodies, acting as amicus curiae, possess unparalleled institutional expertise and constitute a valuable

[1] *Liberty Lincoln Mercury, Inc. v. Ford Mktg. Corp.*, 149 F.R.D. 65, 82 (D.N.J. 1993).

[2] *See United States v. Alkaabi*, 223 F. Supp. 2d 583, 592 (D.N.J. 2002) (stating that "the Third Circuit's application of Fed. R. App P. 29… provides guidance to this Court").

[3] Fed. R. App. P. 29(a)(2).

[4] *See, e.g., Clark v. Actavis Group HF*, 567 F. Supp. 2d 711, 718 n.11 (D.N.J. 2008) (accepting amicus brief filed by U.S. Department of Justice, citing Fed. R. App. P. 29).

means of determining how the court's decision may affect the world outside its chambers."[5]

II. The Court Should Exercise its Discretion to Accept an FTC *Amicus* Brief

Courts in this district typically approve amici participation when: "(1) the amicus curiae has a 'special interest' in the particular case; (2) the amicus curiae's interest is not represented competently or at all in the case; (3) the proffered information is timely and useful; and (4) the petitioner is not partial to a particular outcome in the case."[6] The FTC satisfies these criteria..

First, as an independent commission charged with protecting competition, the FTC has a special interest, and a long history of expertise, in the broad competitive implications of abuse of the Hatch Waxman patent listing process, including with regard to improper Orange Book patent listings. Over the last two-plus decades, the FTC has sued over improper patent listings,[7] conducted an

[5] Michael K. Lowman, *The Litigating Amicus Curiae: When Does the Party Begin After the Friends Leave?*, 41 Am. U. L. Rev.1243, 1261–62 (1992).
[6] *Prof'l Drug Co. Inc. v. Wyeth Inc*., No. 11–5479, 2012 WL 4794587, *1 (D.N.J. 2012) (quoting *Liberty Res., Inc. v. Philadelphia Hous. Auth.*, 395 F. Supp. 2d 206, 209 (E.D. Pa. 2005)).
[7] *See In re Biovail Corp*., FTC Dkt. No. C-4060 (Oct. 2, 2002).

industry study,[8] and filed multiple amicus briefs relating to the issue.[9] In September 2023, the FTC issued a policy statement concerning improper Orange Book listings and the resulting competitive consequences, explaining that using inappropriately listed patents in the Orange Book to obtain a 30-month stay of competition may have serious long-term implications for all consumers, not just the private parties in this case.[10] In addition, as part of a November 2023 effort to address more than 100 Orange Book improper patent listings by 10 pharmaceutical companies, FTC staff recently disputed Orange Book listings for the specific patents at issue in this case using FDA regulatory procedures available to any person.[11] Concurrently, FTC staff sent these companies, including Teva, letters

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[8] *See* Fed. Trade Comm'n, Generic Drug Entry Prior to Patent Expiration: An FTC Study, 39-52 (2002), https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patentexpiration-ftc-study/genericdrugstudy_0.pdf.

[9] Mem. of Law of Fed. Trade Comm'n as *Amicus Curiae* Opposing Defendant's Mot. to Dismiss, *In re: Buspirone Patent Litig.*, No. 1:01-md-1410, ECF No. 31 (S.D.N.Y. Jan. 8, 2002); Fed. Trade Comm'n's Brief as Amicus Curiae, *Jazz Pharms. Inc. v. Avadel CNS Pharms., LLC*, C.A. No. 1:21-cv-00691, ECF No. 222-3 (D. Del. Nov. 10, 2022); Fed. Trade Comm'n's Brief as Amicus Curiae, *Mylan Pharms. Inc., et al. v. Sanofi-Aventis U.S. LLC, et al.*, C.A. No. 2:23-cv-00836, ECF No. 61-3 (W.D. Pa. Nov. 20, 2023).

[10] Fed. Trade Comm'n. Statement Concerning Brand Drug Manufacturers' Improper Listing of Patents in the Orange Book (Sept. 14, 2023) ("FTC Orange Book Statement") https://www.ftc.gov/system/files/ftc_gov/pdf/p239900orangebookpolicystatement092023.pdf.

[11]. *See* Fed. Trade Comm'n, Press Release, FTC Challenges More Than 100 Patents As Improperly Listed in the FDA's Orange Book (Nov. 7, 2023),

informing them of the regulatory disputes and requesting that they remove the improper patent listings from the Orange Book.[12]

As the primary antitrust enforcer in the pharmaceutical industry, the FTC has a special interest in the interpretation of laws impacting generic drug competition. Courts consider these interests when granting motions for leave to federal agencies to participate as amicus curiae.[13]

Second, the Commission's interests, and the public interest, are not adequately represented by the private parties litigating this case. The parties are each pharmaceutical companies representing their own business interests. The Commission, on the other hand, is a federal agency charged with protecting consumers from practices that create anticompetitive conditions and raise prices. Improper submission of patents for listing in the Orange Book may impair competitive conditions and result in higher costs to consumers.[14]

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https://www.ftc.gov/news-events/news/press-releases/2023/11/ftc-challenges-more-100-patents-improperly-listed-fdas-orange-book

[12] *Id.*

[13] *See, e.g.*, *Waste Mgmt. of Pa., Inc. v. City of York*, 162 F.R.D. 34, 37 (M.D. Pa. 1995) (stating as a basis for accepting an amicus brief that "the EPA has a special interest in this litigation as it is the primary body responsible for administering and enforcing" the relevant law).

[14] *See* FTC Orange Book Statement, *supra* note 10, at 1; Fed. Trade Comm'ns Br. as Amicus Curiae, *Jazz Pharms. Inc. v. Avadel CNS Pharms., LLC*, C.A. No. 1:21-cv-00691, ECF No. 222-3 (D. Del. Nov. 10, 2022).

Third, the proposed amicus brief provides useful information based on the FTC's extensive knowledge of pharmaceutical competition. The brief outlines the relevant regulatory structure, explains how the regulatory setting may influence antitrust analysis, addresses proper legal standards for listing patents in the Orange Book, and explains that Amneal's antitrust counterclaims are not supplanted by the Hatch Waxman Act.

The FTC's motion for leave is also timely because the Court granted the FTC's consented-to request to file this motion for leave today, March 22, 2024.[15] Teva is not prejudiced by the filing of this brief, particularly since subsequent to the Court's granting the FTC permission to file for leave, Teva received an extension on its next brief until April 15, 2024.[16] Hence, Teva will have more than three weeks to consider and respond to the attached amicus brief. Lack of prejudice is strongly reinforced by Teva's non-opposition to this motion.

Fourth, the FTC does not take a position on the ultimate outcome of the commercial dispute between the parties in this case. Although the FTC takes the position that the Orange Book listings for the asserted patents are improper and such listing may provide a basis for standalone antitrust claims, and has a strong

[15] Order Granting the Fed. Trade Comm'n Permission to File a Mot. Seeking Leave to File an Amicus Br., ECF No. 54.

[16] Letter Order, ECF No. 58 (minute order providing Teva's "consolidated opposition papers to Amneal's motion and reply brief due on 4/15/2024").

interest in the sound development of the law in this area,[17] the FTC takes no position on Teva's patent infringement claims or the amount of damages, if any, that should be awarded to either party on its claims or counterclaims.

III. Conclusion

For the foregoing reasons, the FTC respectfully requests the Court grant it leave to file the attached brief as amicus curiae.

Dated: March 22, 2024

Respectfully submitted,

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[17] Courts "regularly allow[]" amicus filings advocating "policy interests" like the FTC's here. *Alkaabi*, 223 F. Supp. 2d at 592.

CERTIFICATE OF SERVICE

Pursuant to Local Rule 5.2(14)(b)(1), I, Bradley J. Vettraino, an attorney with the Federal Trade Commission, hereby certify that the foregoing document was served on all counsel of record through the Court's CM/ECF system on March 22, 2024.

/s/ Bradley J. Vettraino
Bradley J. Vettraino